Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0648347	08/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Wpm Pathology Laboratory, Chartered	338 North Front St, Salina, KS	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with Testing Personnel (TP) #8, the laboratory failed to ensure the hematoxylin and eosin (H&E) stain, special stain, and immunohistochemical (IHC) stain policies and procedures addressed the preparation of slides, solutions, controls, reagents, stains, and other materials used in testing; the corrective actions to take when control results failed to meet the laboratory's criteria for acceptability; and the laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or

	alert values. Findings Include: 1. Review of the H&E, IHC, and special stain policies and procedures provided to the Surveyor by TP #8 titled "Evaluation of Histology Stain" and "Documentation of Immunohistochemical (IHC) Tissue Control Stain Reactivity" found the policies lacked: - The preparation of slides, solutions, controls, reagents, stains, and other materials used in testing - The corrective actions to take when control results failed to meet the laboratory's criteria for acceptability - The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values 2. When the Surveyor requested the manufacturer's package insert instructions for the special stains used in histopathology from TP #8, TP #8 stated the laboratory did not have any package insert instructions for the reagents used in histopathology. The interview occurred 08/28/2018 at 10:53 AM.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation and interview with Testing Personnel (TP) #8, the laboratory failed to label histopathology reagents, solutions, control materials, and other supplies to indicate their storage requirements, preparation dates, and expiration dates. Findings Include: 1. Direct observation of the histopathology laboratory staining area on the date of survey at 10:50 AM found 40 reagents, stains, and solutions on the counters, at room temperature that were not labeled to indicate their storage requirements, preparation dates, and expiration dates as follows: - Safranin O Solution - 70% ET-OH - Phosphomolydic Acid - PTAH Hematoxylin Phosphotungstic Acid DH2O - Geimsa solution - 12% Glacial Acetic Acid - Jenner solution - 0.5% Periodic Acid - 3% Glacial Acetic Acid - Alcian Blue - Colloidal Iron - 2% Hydrochloric Acid - Weigert's Iodine - Potassium Permaganate 0.25% - 1% Congo Red - 1% Sodium Hydroxide - Verhoeff van Geison - Ferric Chloride - Oxalic Acid 5% - 10% Glacial Acetic Acid - 1% Basic Fuchsin - 5% Hematoxylin in alcohol - Aniline Blue - 29% Ferric Chloride - Light Green SF - Biebrich Scarlet - 1% Aqueous Methylene Blue - Mentanil Yellow (Mucicarmine) - Kinyoun's Carbol Fuchsin - Crystal Violet (Stock) - 1% Alician Blue in 3% Acetic Acid - Toluidine Blue - 1% Crystal Violet - Gram's Iodine - Fites Carbol - 0.5% Basic Fuchsin - Bouin's Solution - GMS stain - Schiff's reagent - 50% Alcohol 2. TP #8 confirmed the histopathology stains and reagents were not labeled with storage requirements, preparation dates, and expiration dates. The interview occurred 08/28/2018 at 10:59 AM.